

AGENDA

Third Meeting of the Secretary's Advisory Committee on Xenotransplantation

November 29-30, 2001
Sheraton Columbia Hotel, Columbia, Maryland

DAY 1– Open Session

- 8:30 am **Opening Remarks**
Dr. Harold Vanderpool (SACX Chair)
- 8:40 am **Pilot U.S. National Xenotransplantation Database: Update and Demonstration**
Dr. Eda Bloom (Center for Biologics Evaluation and Research, FDA) – Concept, Objectives, Status
Mr. Tom Kruthers (TRW/Stellar Systems, under contract to FDA) – Demonstration
- 9:40 am **Centralized Xenotransplantation Biological Archive: Update and Discussion**
Dr. Louisa Chapman (National Center for Infectious Diseases, CDC)
- 10:15 am **Ethics Training for Committee Members**
Dr. Mary Groesch (Executive Director, SACX) – Conflict of Interest
Ms. Holli Beckerman Jaffe (Office of General Counsel, DHHS) – Confidentiality
- 10:30 am Break
- 10:45 am **Xenotransplantation: Meeting Updates, News, and Advances**
- Highlights of the VI Congress of the International Xenotransplantation Association*
Dr. David, K.C. Cooper (Harvard Medical School, and Editor, Xenotransplantation)
- Infection in Xenotransplantation—Recent Data*
Dr. Jay Fishman (Harvard Medical School)
- Highlights of NHLBI Workshop on Xenotransplantation*
Dr. Judith Massicot-Fisher (National Heart, Lung and Blood Institute, NIH)
- Xenotransplantation Consortium Concept*
Dr. Robin Pierson (Vanderbilt University Medical Center)
- Highlights of the Recent Vatican Position Statement on Xenotransplantation*
Dr. Harold Vanderpool (SACX Chair)

- 12:30 pm Lunch
- 1:45 pm **Introduction to SACX Working Groups**
- SACX WG on the State of the Science in Xenotransplantation*
Dr. Jon Allan or Dr. Megan Sykes (SACX Members, WG Co-chairs)
- SACX WG on Informed Consent Issues in Xenotransplantation*
Ms. Robyn Shapiro or Dr. Harold Vanderpool (SACX Members, WG Co-chairs)
- 2:00 pm **Concurrent Working Group Breakout Sessions**
- 4:00 pm Break / Working Groups to develop talking points
- 4:20 pm **Reports of WGs and Plenary Discussion**
- 5:35 pm **Public Comment**
- 5:50 pm Adjourn until morning

DAY 2 – Open Session

- 8:30 am **FDA Overviews and Plenary Discussion**
- Xenotransplantation IND Overview*
Dr. Eda Bloom (Center for Biologics Evaluation and Research, FDA)
- An Example of a Xenotransplantation Product Involving Ex Vivo Contact with a Well Characterized Cell Line*
Dr. Peter Hudson (FDA Center for Devices and Radiological Health)
- Screening for Retrovirus in Xenotransplantation: Overview of Processes and Experiences*
Dr. Carolyn Wilson (Center for Biologics Evaluation and Research, FDA)
- 10:30 am **Closing Remarks**
Dr. Harold Vanderpool

DAY 2 – Closed Session

- 10:30 am **FDA Briefing on Xenotransplantation Clinical Research**
(FDA Staff)
- 2:00 pm Meeting Closes